PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference E1-A0410Y1P	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/JP2005/001887	International filing date *(day/month/year)* 09 February 2005 (09.02.2005)	Priority date *(day/month/year)* 09 February 2004 (09.02.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant EISAI R & D MANAGEMENT CO., LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 19 September 2006 (19.09.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Masashi Honda e-mail: pt08@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference E1-A0410Y1P	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2005/001887	09.02.2005	09.02.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant
EISAI R & D MANAGEMENT CO., LTD.

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP Facsimile No.	Authorized officer Telephone No.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/001887

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☒ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Box No. III **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. parts of 1-3, 5, 7, 10, 12, 14, 17, 19, 22, 24, 27, 29, 32, 34, 36-45 and 47-52

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

Parts of claims 1-3, 5, 7, 10, 12, 14, 17, 19, 22, 24, 27, 29, 32, 34, 36-45 and 47-52 are either not clearly described or not sufficiently supported by the DESCRIPTION. Since these claims are not clearly and fully disclosed in the DESCRIPTION, no international search was conducted therefor. The reasons are presented in Box VIII.

☒ the claims, or said claims Nos. parts of 1-3, 5, 7, 10, 12, 14, 17, 19, 22, 24, 27, 29, 32, 34, 36-45 and 47-52 are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. parts of 1-3, 5, 7, 10, 12, 14, 17, 19, 22, 24, 27, 29, 32, 34, 36-45 and 47-52

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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PCT/JP2005/001887

Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-52	YES
	Claims		NO
Inventive step (IS)	Claims	1-52	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-52	YES
	Claims		NO

2. Citations and explanations:

None of the documents cited in the international search report describes the inventions of claims 1-52, and because these matters are not obvious to persons skilled in the art, the inventions of these claims are novel and involve an inventive step. More specifically, none of the documents discloses that relaxin-3 has the effect of promoting eating, increasing body weight, and increasing the amount of fat.

WRITTEN OPINION OF THE
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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-3, 5, 10, 14, 17, 22, 27 and 32

With respect to the "functionally equivalent modified peptide" in the above claims, the DESCRIPTION states the following: "a functionally equivalent modified peptide means...a polypeptide comprising an amino acid sequence having deletion, substitution, insertion and/or addition of one or more amino acids...and having substantially the same activity...as relaxin-3" (Par. No. 0013). However, it is very unlikely, for example, that a polypeptide having mutations in a large number of amino acids still sustains an activity equivalent to the original polypeptide. Thus, it is unclear which polypeptides and which specific structures thereof correspond to the polypeptide according to these claims and an excessively large amount of trial-and-error will be needed for a person skilled in the art to obtain such a polypeptide. Thus, this authority finds that the above claims are not clearly described. Furthermore, this authority finds that the inventions of above claims are neither sufficiently supported by the DESCRIPTION nor fully disclosed therein in a manner sufficiently clear and complete for the inventions to be worked by a person skilled in the art.

No search was made on the inventions of the claims that are not clearly described and are neither sufficiently supported by the DESCRIPTION nor fully disclosed therein.

Claims 1-3, 5, 10, 14, 17, 22, 27 and 32

With respect to the "polypeptide comprising an amino acid sequence with a homology of 70% or above" in the above claims, it is very unlikely that a polypeptide with a homology of about 70% still sustains an activity equivalent to the original polypeptide. Thus, it is unclear which polypeptides and which specific structures thereof correspond to the polypeptide according to these claims and an excessively large amount of trial-and-error will be needed for a person skilled in the art to obtain such a polypeptide. Thus, this authority finds that the above claims are not clearly described. Furthermore, this authority finds that the inventions according to the above claims are neither sufficiently supported by the DESCRIPTION nor fully disclosed therein in a manner sufficiently clear and complete for the inventions to be worked a person skilled in the art.

No search was made on the inventions of the claims that are not clearly described and are neither sufficiently supported by the DESCRIPTION nor fully disclosed therein.

Claims 7, 12, 19, 24, 29 and 34

It is unclear what part corresponds to the "part" in the above claims. Thus, this authority finds that the above claims are not clearly described. Moreover, the inventions according to the above claims involve partial polypeptides not capable of binding to relaxin-3, and thus it is unclear how such an invention can be worked. Accordingly, this authority finds that the inventions according to the above claims are neither sufficiently supported by the DESCRIPTION nor fully disclosed therein in a manner sufficiently clear and complete for the inventions to be worked a person skilled in the art.

No search was made on the inventions of the claims that are not clearly described and are neither sufficiently supported by the DESCRIPTION nor fully disclosed therein.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box VIII.

Claims 36, 38, 40, 42 and 44

It is unclear what specific compounds correspond to the "compound having an SALPR inhibitory effect" in the above claims. Even after looking at the EXAMPLES and the like, there is no explanation of what substances other than "Compound 1" have an SALPR inhibitory effect in practice. An excessively large amount of trial-and-error will be needed for a person skilled in the art to obtain such a substance other than "Compound 1" having an SALPR inhibitory effect. Thus, this authority finds that the above claims are not clearly described. Furthermore, this authority finds that the inventions according to the above claims are neither sufficiently supported by the DESCRIPTION nor fully disclosed therein in a manner sufficiently clear and complete for the inventions to be worked a person skilled in the art.

No search was made on the inventions of the claims that are not clearly described and are neither sufficiently supported by the DESCRIPTION nor fully disclosed therein.

Claims 37, 39, 41, 43 and 45

It is unclear what specific compounds other than "compound 1" shown in the EXAMPLES and the like correspond to the "compound obtained by the screening method" in the above claims. Thus, this authority finds that the above claims are clearly described. Furthermore, this authority finds that the inventions according to the above claims are neither sufficiently supported by the DESCRIPTION nor fully disclosed therein in a manner sufficiently clear and complete for the inventions to be worked a person skilled in the art.

No search was made on the inventions of the claims that are not clearly described and are neither sufficiently supported by the DESCRIPTION nor fully disclosed therein.

Claims 47 to 52

It is unclear what specific compounds other than "relaxin-3" correspond to the "compound acting on a realixn-3 receptor" in the above claims. Thus, this authority finds that the above claims are not clearly described. Furthermore, this authority finds that the inventions according to the above claims are neither sufficiently supported by the DESCRIPTION nor fully disclosed therein in a manner sufficiently clear and complete for the inventions to be worked a person skilled in the art.

No search was made on the inventions of the claims that are not clearly described and are neither sufficiently supported by the DESCRIPTION nor fully disclosed therein.